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K053213

JUL - 6 2006

510(K) Summary Statement for Bi-Ostetic™ Foam

In accordance with the Food and Drug Admisnistration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of Bi-Ostetic Foam.

Submitted By:	Berkeley Advanced Biomaterials, Inc.
Date:	10 October 2005
Contact Person:	François Génin, Ph.D.
Position:	Chief Executive Officer
Contact Information	Phone: 510-883-0500; Fax: 510-883-0511
Proprietary Name:	Bi-Ostetic Foam
Regulation Name:	Resorbable Calcium Salt Bone Void Filler Device
Regulation Number:	888.3045
Classification:	Class II
Device Code/ Panel Code:	Orthopedics/87/MQV

DEVICE INFORMATION

A. INTENDED USE

Bi-Ostetic Foam is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. The product should be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process. The bone graft can be mixed with autogenous bone marrow prior to use at the physician's discretion. In weight bearing situations, Bi-Ostetic Foam is to be used in conjunction with internal or external fixation devices. The fracture defect treated with Bi-Ostetic Foam should not exceed 30 mL.

B. DEVICE DESCRIPTION

Bi-Ostetic Foam is a bone void filler consisting of resorbable purified fibrillar collagen and resorbable hydroxyapatite/tri-calcium phosphate granules. The bovine fibrillar collagen component is biocompatible. The device provides a scaffold around which new bone can grow.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, materials and design features of Bi-Ostetic Foam are substantially equivalent to the predicate devices previously cleared for market. The safety and effectiveness of Bi-Ostetic Foam are adequately supported by the substantial equivalence information provided within the Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2006

Berkeley Advanced Biomaterials, Inc.
c/o Francois Genin, Ph.D.
Chief Executive Officer
901 Grayson Street, Suite 101
Berkeley, California 94710

Re: K053213/S1
Trade/Device Name: Bi-Ostetic Foam
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: June 9, 2006
Received: June 13, 2006

Dear Dr. Genin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Bi-Ostetic Foam**

Indications for Use:

Bi-Ostetic Foam is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. The product should be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process. The bone graft can be mixed with autogenous bone marrow prior to use at the physician's discretion. In weight bearing situations, Bi-Ostetic Foam is to be used in conjunction with internal or external fixation devices. The fracture defect treated with Bi-Ostetic Foam should not exceed 30 mL.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K052215